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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,739	10/20/2000	Thomas Valentine McCarthy	1377-156P	3757
2292	7590	12/23/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			TUNG, JOYCE	
PO BOX 747			ART UNIT	
FALLS CHURCH, VA 22040-0747			PAPER NUMBER	
			1637	
DATE MAILED: 12/23/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/673,739	Applicant(s) MCCARTHY ET AL	
	Examiner Joyce Tung	Art Unit 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The applicant's response filed 9/30/2005 to the Office action has been entered. Claims 1-21 and 23 are pending.

1. The rejection of claims 1-21 and 23 under 35 U.S.C. 112, first paragraph is withdrawn because of the amendment.
2. The rejection of claims 1-21 and 23 under 35 U.S.C. 112, second paragraph is withdrawn because of the amendment.
3. The rejection of claims 1-21 and 23 under 35 U.S.C. 102(b) as being anticipated by Dianov et al. (Molecular and Cellular Biology, 1992, Vol. 12(4), pg. 1605-1612) is withdrawn because of the amendment.

### **NEW GROUNDS OF REJECTIONS NECESSETATED BY THE AMENDMENT**

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
5. Claims 1-21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - a. Claims 1-21 and 23 are vague and indefinite because it is unclear what is meant by the phrase "the sequence of the extendible fragment is determined by the sequence of the template nucleic acid". Clarification is required.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dianov et al. (Molecular and Cellular Biology, 1992, Vol. 12(4), pg. 1605-1612) in view of McCarthy et al. (5,952,176, issued September 14, 1999).

Dianov et al. disclose that the extent and location of DNA repair synthesis in a double stranded oligonucleotide containing a single dUMP residue have been determined in which the repair pathway of a dUMP residue in DNA involves uracil- DNA glycosylase and incision of the phosphodiester bond 5' to AP site by an AP endonuclease and baseless sugar-phosphate residue could be excised by a dRpase or a 5'-3'exonuclease to leave a hydroxyl group at the 3' terminus (See pg. 1606, fig. 1) and then the polymerase step occur either after or before the excision step.

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The excision step is catalyzed usually by a DNA deoxyribophosphodiesterase (See pg. 1605, the Abstract).

Dianov et al. do not disclose that the modified base is introduced by enzyme extension of the molecule on a template nucleic acid.

McCarthy et al. disclose a novel process for the detection of known mutation and polymorphisms in DNA. The process involves amplification, which incorporates modified precursor nucleotides into the amplified products. The amplified products are one or more glycosylase substrate (See column 5, lines 7-9 and column 5, lines 49-60).

One of ordinary skill in the art would have been motivated by applying enzymatic extension of the DNA molecule on a template nucleic acid to introduce a modified base as taught by McCarthy et al. because the method of McCarthy can be used to detect multiple known mutations by using a single enzyme and a single process (See column 5, lines 18-20). It would have been prima facie obvious to apply enzymatic extension of the DNA molecule on a template nucleic acid to introduce a modified base for characterizing nucleic acid sequence.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### Summary

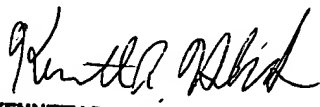
9. No claims are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung  
December 14, 2005

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER  
12/20/05